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ABSTRACT

This report presents: (1) a review of the evidence that vaccine cost has prevented children from being immunized on time; (2) an evaluation of the implementation of the Vaccines For Children (VFC) program, including whether this program, as implemented, is likely to meet the needs of the under-immunized children; and (3) some options for improving vaccine delivery to them. Following an executive summary, chapter 1 describes the Vaccines For Children program and its background. Chapter 2 examines vaccine cost as a barrier to child immunization. Chapter 3 looks at variations and problems in implementation of the VFC program. Options for reducing missed opportunities and improving immunization rates are suggested in chapter 4. The final chapter offers concluding comments and issues for consideration. (TJQ)

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Report to Congressional Requesters

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June 1995

VACCINES FOR CHILDREN

Reexamination of Program Goals and Implementation Needed to Ensure Vaccination

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United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-261272

June 15, 1995

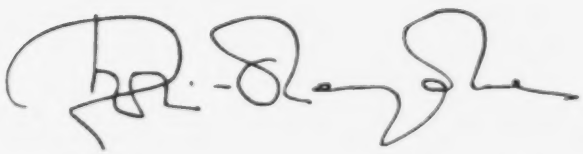
The Honorable Dale Bumpers
United States Senate

The Honorable Scott Klug
The Honorable Ron Wyden
House of Representatives

In response to your request, this report presents (1) our review of the evidence that vaccine cost has prevented children from being immunized on time; (2) our evaluation of the implementation of the Vaccines For Children program, including whether this program, as implemented, is likely to meet the needs of underimmunized children; and (3) some options for improving vaccine delivery to them.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of the Health Care Financing Administration, the Director of the U.S. Public Health Service, and the Director of the Centers for Disease Control and Prevention. Copies will be made available to others upon request.

If you have any questions or would like additional information, please call me at (202) 512-3092. Other major contributors to this report are listed in appendix II.



Kwai-Cheung Chan
Director for Program Evaluation
in Physical Systems Areas

Executive Summary

Purpose

More than 95 percent of the nation's children receive recommended vaccinations by the time they enter school. However, preschool children were overrepresented in the widespread measles outbreaks of 1989-91 and this was attributed to their underimmunization. In conjunction with the Children's Immunization Initiative (CII), VFC is intended to improve children's immunization coverage by reducing the cost of vaccine for their parents. At the request of Senator Dale Bumpers and Representatives Scott Klug and Ron Wyden, GAO reports on (1) the extent to which vaccine cost has prevented children from being immunized on schedule, (2) VFC's implementation and whether VFC, as implemented, can ensure the timely vaccination of underimmunized children, and (3) promising options for improving their immunization rates.

Background

Section 13631 of the Omnibus Budget Reconciliation Act of 1993 created VFC as an entitlement program to provide free vaccine to children 18 and younger who are eligible for Medicaid or who are American Indians or uninsured. Underinsured children (those whose insurance does not cover childhood vaccinations) are also eligible for VFC vaccines but may receive them only in federally qualified health centers or rural health clinics. VFC's fiscal year 1995 cost estimates included $412 million for vaccine purchase and $45.3 million for administrative expenses, such as vaccine distribution, vaccine ordering, and operations. The VFC legislation (signed in August 1993) mandated that the program begin operation by October 1, 1994.

The vaccines VFC currently provides to the states include antigens for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, hepatitis B, and haemophilus influenza according to a schedule set by the Advisory Committee on Immunization Practices (ACIP) of the Public Health Service. The Centers for Disease Control and Prevention (CDC) has announced that doses of influenza vaccine for high-risk children and hepatitis B vaccine for adolescents will be added in fiscal year 1996, along with speedier catch-up immunization against measles. Newly approved varicella (chicken pox) and hepatitis A vaccines will be considered. Only one of these five new additions to the vaccine schedule (the measles booster) will be covered by statutory price caps (that is, contract prices that were in effect in 1993). CDC officials estimate that VFC purchases of the new varicella vaccine could cost an additional $35 million to $560 million, depending on the extent of catch-up coverage ACIP recommends. CDC estimates that once catch-up has been completed, the annual cost of including varicella will range from $35 million to $70 million.

Results in Brief

From the available evidence, GAO concludes that the cost of vaccine for parents has not been a major barrier to children's timely immunization. Moreover, VFC's implementation remains incomplete in six of the seven critical areas GAO reviewed. VFC's automation, accountability, and evaluation mechanisms cannot measure its provision of vaccine to children who are at high risk of underimmunization, nor can they attribute changes in age-appropriate immunization rates to VFC. Thus, CDC cannot ensure that VFC will reach pockets of need—areas or populations in which immunization rates are low and the risk of disease is consequently high. VFC's shortcomings raise questions about its capacity to control vaccine waste and abuse.

Other options may hold better promise than VFC for improving timely vaccination among children, potentially at lower public cost, by reducing missed opportunities for immunization through Medicaid, public health clinics, and other providers with whom underimmunized children already have contact. Moreover, CDC's analysis shows that less than 1 percent of U.S. counties reported measles cases in each year of the 1980s, suggesting that specific efforts might be efficiently targeted to improving immunization in such areas.

Principal Findings

Vaccine Cost

GAO did not find sufficient evidence to conclude that the cost of vaccine for parents has been a major barrier to children's timely immunization. Immunization rates for preschool children at the outset of VFC were at or near the 90-percent national goals for 1996. Further, immunization rates among school children exceed 95 percent for all antigens in the basic series. CDC-sponsored studies clearly demonstrate that, since underimmunized children generally had access to free vaccine before VFC began, cost is less important than missed opportunities for vaccination during their regular contacts with their health care providers. The literature does identify many barriers, including parents' lack of awareness of their children's vaccination schedule, inadequate resources (for example, insufficient clinic staff, insufficient or inconvenient clinic hours, and inaccessible clinic locations), clinic policies that deter vaccination by requiring appointments or refusing to see walk-in patients, and various factors that cause providers to miss opportunities to immunize children at regular visits.

The evidence CDC has cited to document that vaccine cost is a major barrier generally fails to separate vaccine costs, which VFC addresses, from the larger provider fees associated with immunization, which it generally does not. The statute does stipulate that providers may not deny vaccine to a child who is unable to pay the administration fee. However, CDC has no measures to ensure the providers' compliance with this requirement.

It is important to note that in certain population groups and areas, often referred to as pockets of need, disproportionate numbers of children are not immunized for specific diseases, creating conditions ripe for outbreak. For example, CDC's analysis of the measles outbreaks in the 1980s shows that delayed immunization led to consistently reported cases over 10 years in only 17 of 3,137 U.S. counties, suggesting that special efforts to improve immunization coverage might be targeted there.

Program Implementation

Although CDC has devoted considerable effort and resources to implementing VFC, and has made progress, implementation remains incomplete, despite assurances to the contrary following GAO's July 1994 review of VFC. In this subsequent review, as of March 1, 1995, provider enrollment, the development of provider reimbursement policy, order processing and automation arrangements, a vaccine distribution system, accountability provisions, and evaluation planning—six of VFC's seven critical implementation tasks—remained incomplete. The only completed task is contract negotiation for the purchase of vaccines.

CDC and many states cannot gauge the proportion of private immunization providers or Medicaid providers that have been enrolled. Fifteen jurisdictions cannot distribute vaccine to private providers. The physician reimbursement policy is inconsistent with the law. Order-processing software that CDC developed without analyzing its users' requirements has failed to meet their needs. CDC cannot ensure that the program reaches only entitled children or that providers will serve all entitled children. It cannot distinguish between the number of children immunized and the number of doses of vaccine distributed. The states' data on providers' vaccine needs overestimate the number of potentially eligible children and the number of doses needed to immunize them. Finally, although CDC has not released evaluation plans, it is unlikely that the program's effect can ever be assessed because important baseline data were not collected prior to its implementation and because other efforts to improve immunization were initiated concurrently. In the 12 states that already had implemented universal vaccine distribution systems, it is not clear that VFC will have any

direct effect on immunization activities apart from changing the source of their financing. It is conceivable, however, that these states will add newly recommended vaccines to their programs more quickly than they would have when state funding was required.

Promising Options

CDC-funded studies have shown promise for improving immunization rates by coordinating immunization services with large public programs—such as the Special Supplemental Food Program for Women, Infants, and Children and Aid to Families with Dependent Children, which cover children who are known to be at high risk of delayed immunization. Research also links improved immunization with provider-based strategies, such as assessing clinic immunization practices and offering feedback or creating reminder and recall systems or registries to reduce missed opportunities for immunization. One CDC official has testified, based on major CDC-funded research, that immunization rates for most antigens could be improved by as much as 15 percent simply by eliminating missed opportunities.

Matters for Congressional Consideration

The Congress may want to consider refocusing VFC's goal from the improvement of general immunization rates to the achievement of higher immunization rates in pockets of need, where conditions are ripe for disease outbreaks among underimmunized children. Targeting immunization to pockets of need should be more cost-effective than the current approach. In conjunction, enrollment, accountability, automation, and evaluation efforts need to be focused on children who are at greatest risk for delayed immunization. Reminder and recall or tracking systems might help identify and reach them.

Agency Comments

GAO shared a draft of this report with responsible officials of the Department of Health and Human Services (HHS) on June 10, 1995, and received oral comments from them on June 13, 1995. (GAO also orally summarized its findings in an exit conference with HHS officials on May 2, 1995, and received oral comments.) The officials stated that they did not agree with GAO's conclusions and believed that its views were not balanced. However, the comments they provided were directed primarily to tone and technical matters; these comments have been incorporated in the final report where appropriate.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
AFDC	Aid to Families with Dependent Children
CDC	Centers for Disease Control and Prevention
CII	Children's Immunization Initiative
DTP	Diphtheria and tetanus toxoids and pertussis vaccine
GAO	U.S. General Accounting Office
HCFA	Health Care Financing Administration
Hep B	Hepatitis B
HHS	U.S. Department of Health and Human Services
Hib	Haemophilus influenza type B
IAP	Immunization Action Plan
MMC	Mercer Management Consulting
MMR	Measles-mumps-rubella
OPV	Oral polio vaccine
VFC	Vaccines For Children
WIC	Special Supplemental Food Program for Women, Infants, and Children

VFC and Its Background

Senator Dale Bumpers and Representatives Scott Klug and Ron Wyden asked us to (1) assess the evidence that children do not get immunized when they should because vaccine cost is too high, (2) determine the extent to which the Centers for Disease Control and Prevention (CDC) has successfully implemented the Vaccines For Children (VFC) program and whether VFC can help vaccinate underimmunized children on time, and (3) identify promising options for vaccinating those children. Our response starts with brief descriptions of three federal and state programs that operated prior to VFC and the new VFC program, which began operating in 1994.

Three Programs Predating VFC

Before 1994, Medicaid, section 317 of the Public Health Service Act of 1962, and state programs made vaccine free to children. By 1992, almost half the children's vaccine sold in the United States was being bought under these programs. (See table 1.1.) To varying extents, these programs have used contracts between CDC and the vaccine manufacturers to acquire vaccines at prices substantially lower than those charged to private sector purchasers. (See table 1.2.)

Table 1.1: Publicly Purchased Doses of Children's Vaccine as a Percentage of Net Doses Distributed in the United States, 1985-91[a]

Year	DTP	MMR	OPV
1985	15%	38%	32%
1986	29	44	39
1987	45	51	46
1988	33	47	44
1989	35	50	44
1990	40	45	48
1991	43	51	52
1992	[b]	54	45

[a]DTP = diphtheria and tetanus toxoids and pertussis vaccine. MMR = measles-mumps-rubella vaccine. OPV = oral polio vaccine.

[b]Not available.

Source: Division of Immunization, Centers for Disease Control and Prevention, Atlanta, 1993.

Table 1.2: Private Catalog Prices and Federal Contract Prices Per Dose for Children's Vaccines, 1977-92[a]

	DTP		MMR		OPV	
Year	Private	Public	Private	Public	Private	Public
1977	$0.19	$0.15	$6.01	$2.42	$1.00	$0.30
1978	0.22	0.15	6.16	2.35	1.15	0.31
1979	0.25	0.15	6.81	2.62	1.27	0.33
1980	0.30	0.15	7.24	2.71	1.60	0.35
1981	0.33	0.15	9.32	3.12	2.10	0.40
1982	0.37	0.15	10.44	4.02	2.75	0.48
1983	0.45	0.42	11.30	4.70	3.56	0.58
1984	0.99	0.65	12.08	5.40	4.60	0.73
1985	2.80	2.21	13.53	6.85	6.15	0.80
1986	11.40	3.01	15.15	8.47	8.67	1.56
1987	8.92	7.69	17.88	10.67	8.07	1.36
1988	6.47	3.90	19.67	11.74	7.78	1.07
1989	6.09	3.40	19.67	11.74	9.16	1.63
1990	6.09	2.35	19.63	10.27	9.45	1.63
1991	5.41	1.70	20.85	10.89	9.16	1.71
1992	5.41	1.70	20.85	10.89	9.62	1.80

[a]In current dollars, indexed at a base year of 1983. Prices exclude the excise taxes for the Vaccine Injury Compensation Program in effect from 1988 to January 1993. DTP = diphtheria and tetanus toxoids and pertussis vaccine. MMR = measles-mumps-rubella vaccine. OPV = oral polio vaccine.

Sources: Bureau of Labor Statistics, U.S. Department of Labor, Washington, D.C.; Centers for Disease Control and Prevention, Atlanta, 1993.

Medicaid

Low-income children who qualify for Medicaid have been entitled to free immunization since 1965. Today, all children younger than 6 whose family incomes are at or below 133 percent of the federal poverty level can be vaccinated for free under this program. State Medicaid programs have typically set and paid providers a fee to vaccinate these children but have differed in how they purchase Medicaid vaccines. A minority of states have cut costs by buying vaccines in bulk, but in most states, individual Medicaid providers have paid private sector rates to purchase vaccines.[1] Some but not all state Medicaid programs have reimbursed them fully from joint federal and state funds. However, VFC has removed states' need to provide matching funds for Medicaid vaccine payments; vaccines for Medicaid-eligible children may now be financed entirely by the federal government.

Section 317

Any child may be vaccinated for free in a public health clinic under the Federal Immunization Grant Program known as the Section 317 program

[1]See U.S. General Accounting Office, Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost, GAO/HRD-93-41 (Washington, D.C.: March 1993).

because it was established under that section of the Public Health Service Act of 1962. Based on congressional guidance, CDC's allocations over the last 4 years for vaccines under Section 317 have exceeded $700 million ($171 million in 1992, $190 million in 1993, $193 million in 1994, and $149 million in 1995). The states may use their own funds to buy additional vaccine at the heavily discounted federal contract price for use in the public system.

In 1992, state Immunization Action Plans (IAPs) began as blueprints to increase immunization rates. Starting in 1994, substantial CDC grants financed expanded clinic hours and staff, education and outreach for parents and providers, registries and tracking systems, and links between immunization services and other programs. In addition to Section 317 funding for vaccine, federal funding for IAPs and incentive money rose from $46 million in 1992 to $45 million in 1993 and $161 million in 1994; the figure for 1995 is $141 million.

State Programs

Before 1994, when VFC was created, 12 states combined funding from Section 317 and state and local sources to offer free vaccine to all providers for all patients in their practices, including those who are fully insured.[2] In these states, the advent of VFC will increase federal financing, thus reducing the state funds needed to maintain this service.

The Vaccines for Children Program

Section 13631 of the Omnibus Budget Reconciliation Act of 1993 created VFC, to begin by October 1, 1994, to immunize more children and increase vaccine coverage levels nationwide by creating an entitlement to free vaccine for children eligible for VFC and, thereby, reduce vaccine cost as a barrier to immunization. To accomplish this, VFC provides free pediatric vaccine to all enrolled private and public providers.[3] The states can also buy additional vaccine with their own funds at the federal contract price to cover children who are insured.

The program covers children through 18 years of age, but CDC views children younger than 2 as the primary targets. From data CDC collected from the states in January 1994, it appears that about 60 percent of the

[2]Alaska, Connecticut, Idaho, Maine, Massachusetts, New Hampshire, North Carolina, Rhode Island, South Dakota, Vermont, Washington, and Wyoming.

[3]Private providers derive their revenues primarily from billing patients; public providers, such as public health department clinics, derive revenues primarily from public subsidies for general medical care.

eligible children younger than 2 would qualify by being eligible for Medicaid, less than 2 percent as American Indians, 24 percent as uninsured, and 14 percent as underinsured.[4] Many states had difficulty estimating the numbers of children whose insurance was insufficient, and we have not independently reviewed the accuracy of their estimates.

All the children who are now covered by VFC had been able to receive free vaccine through the earlier public programs. Under VFC, uninsured children may now also receive free vaccine from any private provider enrolled in the program, as well as from the public providers from whom it was previously available to them. Underinsured children, however, may receive free VFC vaccine only from federally qualified health centers and rural health clinics. Children eligible for Medicaid were entitled to free vaccine from both public clinics and private providers enrolled in Medicaid. To the extent that these private providers now enroll in VFC, children eligible for Medicaid will continue to receive free vaccine from them, financed now by federal VFC funds rather than federal and state Medicaid funds.

Since VFC is an entitlement program, it has no fixed budget for implementation. However, its cost estimates for fiscal year 1995 included $412 million for vaccine purchase, $24.5 million for vaccine distribution, $9.2 million for vaccine ordering, and $11.6 million for operations.

The vaccines that ACIP was recommending in October 1994 have statutory caps that govern the prices CDC may agree to pay for them. New vaccines, including those for varicella (chicken pox) and hepatitis A, do not. CDC officials estimate that adding varicella vaccine to the recommended schedule could cost VFC between $35 million and $560 million, depending on the breadth of catch-up coverage recommended for children older than 18 months; the ongoing cost would be $35 million to $70 million.[5] CDC has not estimated the cost of adding hepatitis A vaccine, but it is expected to be lower since this vaccine is indicated only for special populations. However, costs will rise further after October 1995 because ACIP has

[4]Although the law refers to "Indians," the program surveys conducted by CDC have referred to "Native Americans and Alaskan Natives."

[5]This estimate presumes that varicella vaccine will cost $15 to $30 per dose, that the recommendation will be fully implemented, and that VFC will cover approximately 60 percent of the population. The estimate has been adjusted to reflect National Health Interview Survey data for 1980-90 indicating the percentage of children who, having contracted chicken pox, therefore have natural immunity. CDC predicts that ACIP is not likely to support catch-up recommendations exceeding $134 million. However, since these estimates were developed, a market price of $39 was announced for varicella, suggesting that the ongoing cost, after meeting catch-up requirements, could be closer to $70 million than to $35 million.

revised its recommendations to include a measles booster shot, an influenza vaccination for high-risk children, and an adolescent dose of hepatitis B.[6]

Objectives, Scope, and Methodology

Our objectives were to (1) assess the extent and quality of evidence that vaccine cost delays immunization, (2) describe CDC's management of VFC's implementation and determine whether CDC's accountability and evaluation mechanisms can ensure that VFC can improve the timely vaccination of underimmunized children, and (3) identify promising ways of immunizing children known to be at high risk of delayed immunization. Our approach to addressing these issues included survey research, site visits, literature syntheses, and review of extant data.

To assess the evidence that vaccine cost delays immunizations, we conducted an extensive review of the literature on barriers to childhood immunization, including synthesis of the four major studies sponsored by CDC in the wake of recent measles epidemics to "diagnose" and identify reasons for low immunization rates among high-risk racial and ethnic minority inner-city preschoolers in Baltimore, Los Angeles, Philadelphia, and Rochester (New York). We reviewed CDC's four studies to assess the factors associated with underimmunization.

Further, we convened a panel of the principal investigators of these studies to help determine the extent to which the cost of vaccine for parents affects their children's vaccination status. In addition, we met with CDC officials and reviewed agency documents, including various types of information CDC cited to address vaccine cost as a cause of delayed immunization. We also reviewed literature and interviewed CDC officials and experts to help identify promising options for improving immunization rates among high-risk preschoolers.

To describe CDC's management of VFC's implementation, we reviewed the extent to which CDC has successfully addressed seven critical tasks: contract negotiation, vaccine distribution, provider enrollment, provider reimbursement, order processing and automation, accountability, and

[6]Two of these vaccines, the adolescent dose of high-risk hepatitis B vaccine and the influenza vaccine, are not covered under statutory price caps because they were not previously incorporated in the ACIP schedule. CDC estimates that the fiscal year 1996 cost of buying vaccines to immunize 30 percent of the target population for high-risk hepatitis B, 70 percent of the target population with an MMR booster, and 40 percent of the target population with influenza vaccine will be $56.85 million.

program evaluation.[7] In December 1994 and January 1995, we conducted two telephone surveys of state immunization officials, one focusing on order processing and automation and the other on the six remaining tasks. The purpose of our survey was to ascertain their progress in implementing the VFC program and any problems they experienced while doing so. Projects in all 50 states and the District of Columbia responded.

To ensure accuracy, we compared the survey responses to data collected by CDC and private sector organizations. We then collected additional necessary data on provider enrollment, distribution, and other implementation issues from CDC and selected states. We interviewed vaccine experts, federal and state officials, and representatives of vaccine manufacturers, vaccine distributors, and physicians. The latter included representatives of the American Academy of Osteopaths and the American Academy of Pediatrics. We also reviewed pertinent written material from the National Medical Association.

To assess CDC's accountability and evaluation mechanisms for VFC, we focused on their ability to ensure that immunization rates improve where the incidence of disease has been relatively high by monitoring the numbers and characteristics of immunized children. We also looked at how these mechanisms help control waste, fraud, and abuse in public and private settings.

Our review was limited in that, although we conducted site visits for the purpose of interviewing state officials, we did not assess the quality of state distribution arrangements. Our work was conducted between August 1994 and May 1995 in accordance with generally accepted government auditing standards.

[7]U.S. General Accounting Office, Vaccines For Children: Critical Issues in Design and Implementation, GAO/PEMD-94-28 (Washington, D.C.: July 1994), pp. 2-3.

Vaccine Cost

Many factors keep children from being immunized on time, but there is not sufficient evidence to conclude that what parents must pay for their vaccine is among the major barriers. For decades, almost all children have had access to free vaccines through either Medicaid or public health clinics. Thus, it appears that just reducing the cost of vaccine, the primary purpose of VFC, will not prevent outbreaks of disease like those of 1989-91. The evidence that CDC has presented at conferences and provided us to substantiate vaccine cost as a barrier to immunization has major problems. Moreover, four important CDC-sponsored studies yield contrary findings.

Evidence From Analysis of Current Immunization Rates

Even prior to VFC, immunization rates for school-age children exceeded 95 percent for all antigens in the basic series, regardless of vaccine cost. A 1994 CDC publication notes that "Immunization levels in children who enter school or are members of other 'captive' populations such as Head Start or day care are greater than 90% and even higher than 95% in many instances, particularly at entry into kindergarten."[1] (See table 2.1.) This is probably attributable to day care, school, and Head Start entry requirements and performance objectives.

Table 2.1: U.S. Immunization Levels, 1991-92 School Year

	Weighted average		
Vaccine	Head Start	Day care[a]	K-1[b]
DTP	93%	94%	96%
Measles-containing	97	96	98
Polio	93	94	97

[a]Licensed day care facilities.

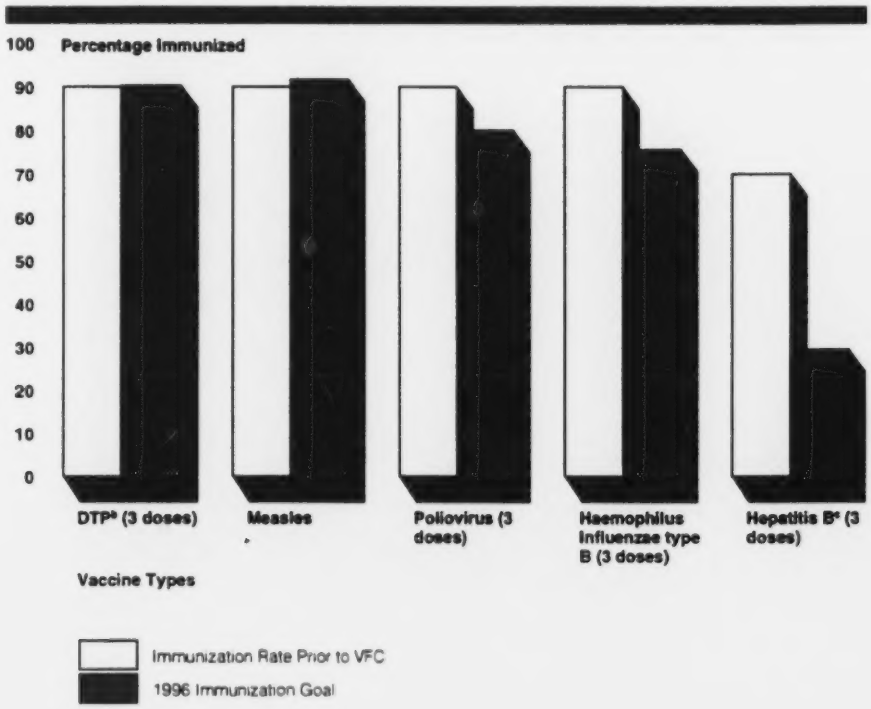
[b]Kindergarten and first-grade immunization assessment.

Source: Centers for Disease Control and Prevention, "The Childhood Immunization Initiative: Charts, Tables, and Graphs," Atlanta, 1994, p. 14.

This suggests that, in at least the school-age group, vaccine cost has not been a barrier to full immunization. Further, even before VFC, 1996 immunization goals for preschool children had already been met for two of the five basic vaccine series, and they had nearly been met for two other vaccines. (See figure 2.1.)

[1]Centers for Disease Control and Prevention, "The Childhood Immunization Initiative: Charts, Tables, and Graphs," Atlanta, 1994, p. 14.

Figure 2.1: Immunization Rates Two Quarters Prior to VFC Implementation Versus 1996 Immunization Goals for Each Recommended Vaccine for Children Ages 19-35 Months[a]



[a]All rates are for the second quarter of 1994, the most recent available data as of May 1995. The Children's Immunization Initiative, launched in April 1993, seeks 90-percent coverage among 2-year-olds by 1996 for four of five major vaccines that the Public Health Service Advisory Committee on Immunization Practices has recommended: one dose of measles-mumps-rubella vaccine and at least three doses each of diphtheria and tetanus toxoids and pertussis vaccine, oral polio virus vaccine, and haemophilus influenza type b vaccine. The goal is 70 percent for three doses of the more recently introduced hepatitis B vaccine.

[b]Diphtheria and tetanus toxoids and pertussis vaccine.

[c]Children born before the recommendation for universal vaccination represented 35 percent of the sample from which this rate was calculated.

Source: Assessment Branch, Data Management Division, National Immunization Program, Division of Health Interview Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention, "Vaccination Coverage Levels Among Children Aged 19-35 Months—United States, April-June 1994," Morbidity and Mortality Weekly Report, May 26, 1995, pp. 396-98.

CDC officials point out that the percentage of preschoolers who have received the full series of recommended vaccines is lower, at 68 percent (for four doses of DTP, three doses of OPV, and one dose of measles-containing vaccine), but we have some concerns about the

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meaning and interpretation of this measure. We believe that this statistic could create a misleading impression of the extent of immunization problems because it counts children who are missing only one dose the same as children who are missing several doses. More important, it is not meaningful in terms of assessing preparedness to prevent specific diseases and tends to conceal the source of problems in children's receiving specific antigens or doses.

This indicates that cost for at least some major vaccines has not been a major barrier to immunization insofar as it has not kept preschool children from timely immunization. Factors other than vaccine cost, such as clinic policies and resources and factors that cause providers to miss opportunities to immunize children during regular visits, may be more salient.

CDC-Sponsored Research

Even in the presence of high general immunization rates, disease can break out locally where there are high concentrations of children who have not been immunized against a particular disease. Following the 1989-91 measles outbreaks, CDC analysis showed that only 17 of 3,137 U.S. counties reported measles cases in 10 consecutive years while 53.9 percent of counties did not report any cases. (See table 2.2.) The counties that reported cases in more years tended to have lower rates of preschool immunization.

Table 2.2: The 17 U.S. Counties Reporting Measles Every Year, 1980-89

State	County	Measles cases	Mean cases per 100,000 population
California	Los Angeles	2,543	3.1
	San Diego	1,370	6.3
	Orange	651	3.0
	San Mateo	103	1.7
	Alameda	100	0.8
	Santa Cruz	47	2.2
Florida	Dade	782	4.4
Hawaii	Honolulu	178	2.2
Illinois	Cook	3,420	6.6
	Du Page	343	4.8
Massachusetts	Middlesex	133	1.0
New York	Kings	1,383	6.1
	Bronx	732	6.2
	Queens	654	3.4
	New York	409	2.8
	Westchester	193	2.2
Texas	Tarrant	194	1.9

Source: Bradley S. Hersh et al., "The Geographic Distribution of Measles in the United States, 1980 Through 1989," Journal of the American Medical Association, 267:14 (April 8, 1992), 1939.

Subsequent to these measles outbreaks, CDC commissioned four studies to find out why preschool children had not been immunized on time in Baltimore, Los Angeles, Philadelphia, and Rochester, New York. These studies identified geographic areas or populations in which the incidence of disease had been relatively high—often referred to as pockets of need—and studied immunization in these areas or groups.[2] The studies found that "financial barriers were not a factor in these low coverage rates" but that "missed opportunities"—visits to providers during which children are not vaccinated despite the absence of

[2]For example, the study in Philadelphia concentrated on about 20 percent of the city's population residing in an area in north-central Philadelphia. The authors note that this area was overrepresented in school-based studies of underimmunization and, ultimately, measles cases. Other studies, in Los Angeles and Baltimore, examined geographic areas in which there were high concentrations of residents meeting certain demographic criteria associated with low immunization or high incidence of disease.

contraindications—were.[3] They found that most of the underimmunized children had access to free vaccine through Medicaid or public health clinics—that is, through private or public providers. They had visited their providers an average of six to eight times during a given year and could have received their scheduled immunizations during these visits, but the providers had failed to vaccinate them.

The four studies identified several factors associated with missed opportunities, including provider and clinic-related factors and policies, such as failure to simultaneously vaccinate or accelerate the immunization of children who were behind schedule, lack of access to children's immunization records, and lack of organizational support. Opportunities for immunization were missed both when children were well and when they were sick, but health care providers were more likely not to vaccinate children when they were sick. In fact, incorrect beliefs about contraindications for immunization were particularly important; in Baltimore, for example, opportunities were missed at approximately 25 to 30 percent of preventive visits but at more than 75 percent of sick-child visits.[4]

Evidence Cited by CDC

As evidence that vaccine cost is a barrier to timely immunization, CDC documents cite

- increases in vaccine cost over the past decade;
- surveys showing the frequency with which private health care providers report referring patients to public health providers for immunization, their

[3]B. Guyer et al., "The Baltimore Immunization Study: Immunization Coverage and Causes of Under-Immunization Among Inner-City Children in Baltimore," contract 200-90-0850, Centers for Disease Control and Prevention, Atlanta, June 1993; D. L. Wood et al., "Increasing Immunization Among Latino and African American Preschool Children in Los Angeles: A Report to the Centers for Disease Control and Prevention," contract 200-90-0850, National Immunization Program, Atlanta, April 1, 1993; Allan M. Arbeter, "Final Report: A Study to Increase Immunization Coverage of Inner-City Minority Children in Philadelphia, Pennsylvania," contract 200-90-0870, Centers for Disease Control and Prevention, Atlanta, July 2, 1993; Klaus Roghmann et al., final report, contract 200-90-0869, Centers for Disease Control and Prevention, Atlanta, June 14, 1993. For more on the Baltimore study, see V. Keane et al., "Perceptions of Vaccine Efficacy, Illness and Health Among Inner City Parents," Clinical Pediatrics, 32 (1993), 2-7; B. Guyer et al., "Immunization Coverage and Preventive Health Care Visits Among Inner-City Children in Baltimore," Pediatrics, 94 (1994), 53-58; N. Hughart et al., "Do Provider Practices Conform to the New Pediatric Immunization Standards?" Archives of Pediatrics and Adolescent Medicine, 148 (1994), 903-35.

[4]Baltimore investigators found that gastroenteritis, otitis media, skin infection, and upper respiratory infection were diagnoses commonly recorded at sick-child visits in which an opportunity to immunize was missed without valid contraindication.

reasons for doing so, and their opinions regarding a universal vaccine purchase program;[5]

- reports from health departments of greater numbers of referrals from private providers;
- surveys of parents at public clinics regarding their reasons for using public health clinics;[6]
- policy studies of the relationship between health insurance coverage, visits to health care providers, and immunization;[7] and
- comparisons of immunization rates between states that do and do not have universal vaccine distribution programs.

In 1993, we pointed out the difficulty of linking higher vaccine costs with changes in immunization rates.[8] Since then, Mercer Management Consulting (MMC), under contract to the U.S. Department of Health and Human Services (HHS), has reported that 69 percent of the increase in the cost of full immunization between 1982 and 1993 is attributable to the addition of new vaccines to the immunization schedule (54 percent) and an excise tax (15 percent). It is true that vaccine prices rose rapidly in the early 1980s, but this growth flattened considerably after the National Vaccine Injury Compensation Program began in 1988; MMC has reported that, since 1988, per dose revenues have not grown faster than inflation for any scheduled pediatric vaccine.

To determine the relationship between timely immunization and a variety of potential barriers, we reviewed studies of the populations of children

[5]H. Ruch-Ross and K. O'Connor, "Immunization Referral Practices of Pediatricians in the United States," Pediatrics, 94:4 (1994), 508-13; W. C. Bordley et al., "Factors Responsible for Immunization Referrals to Health Departments in North Carolina," Pediatrics, 94:3 (1994), 376; P. Szilagyi et al., "Immunization Practices of Pediatricians and Family Physicians in the United States," Pediatrics, 94:4 (1994), 517-23; J. Schulte et al., "Changing Immunization Referral Patterns Among Pediatricians and Family Practice Physicians, Dallas County, Texas, 1988," Pediatrics, 87:2 (1991), 204; P. Arnold and T. Schenkler, "The Impact of Health Care Financing on Childhood Immunization Practices," American Journal of Diseases of Children, 146 (1992), 728; J. Wright and E. Marcuse, "Immunization Practices of Washington State Pediatricians, 1989," American Journal of Diseases of Children, 145 (1992), 1033; S. Rosenbaum et al., Universal Distribution of Childhood Vaccines: The Experience of Twelve States (Washington, D.C.: Center for Health Policy Research, George Washington University, November 1994); R. K. Zimmerman and J. E. Janosky, "Immunization Barriers in Minnesota Private Practices: The Influence of Economics and Training on Vaccine Timing," Family Practice Research Journal, 13:3 (1993), 213-23; R. K. Zimmerman et al., "Barriers to Measles and Pertussis Immunization: The Knowledge and Attitudes of Pennsylvania Primary Care Physicians," Department of Family Medicine and Clinical Epidemiology, University of Pittsburgh School of Medicine, Pittsburgh, 1994.

[6]T. Lieu et al., "Health Insurance and Preventive Care Sources of Children at Public Immunization Clinics," Pediatrics, 93:3 (1994), 373-78.

[7]Rosenbaum et al.; E. Weissman, Falling Through the Safety Net: Insurance Status and Access to Health Care (Baltimore, Md.: Johns Hopkins University Press, 1994).

[8]See our correspondence to the Honorable John Dingell dated July 21, 1993, and the Honorable Dale Bumpers dated July 27, 1993.

who are at high risk of delayed immunization. Research cited by CDC, in contrast, tended to focus on a more narrow investigation of particular factors, such as providers' referral patterns. For the purpose of assessing the role of vaccine costs in delayed immunization, the research CDC cites suffers from several conceptual and methodological problems: (1) failure to distinguish vaccine costs from other fees associated with immunization, (2) inability to determine whether the outcomes actually measured (such as referral to a public health clinic) were valid indicators of eventual failure to receive timely immunization, and (3) reliance on opinion data collected in surveys rather than analysis of the immunization status of representative samples of children.[9]

For example, CDC officials acknowledged that providers' fees in the private sector potentially represent about 60 percent of the total cost of full immunization (about $40 for each office visit and about $15 for administering each dose). However, much of the evidence they cite fails to distinguish between the cost of vaccine, which is addressed by VFC, and provider fees, which generally are not. Similarly, comparisons of immunization rates between states that do and do not practice universal distribution prohibit accounting for other factors that may influence these rates.[10] Finally, most of the studies CDC cited measured physician referral as an unvalidated substitute for measures of delay in immunization; only one of the studies attempted to directly measure the extent of delay in immunization.[11]

This study found that 25 physicians in Minnesota vaccinated insured children earlier with the third dose of DTP but not the first dose of MMR.[12] However, this finding does not directly support a conclusion that time to immunization among the various insurance groups differed because of vaccine cost as opposed to unmeasured characteristics that may be

[9]In fact, other research notes that, in some locations, substantial proportions of parents take their children to public clinics because of delays in receiving appointments with primary providers. (See T. Lieu et al., "Health Insurance and Preventive Care Sources of Children at Public Immunization Clinics," Pediatrics, 93:3 (1994), 373-78.) Moveover, children who clearly have financial access to immunization may nonetheless fail to receive it in a timely manner. (See T. Lieu et al., "Risk Factors for Delayed Immunization Among Children in an HMO," American Journal of Public Health, 84:10 (1994), 1621-25.)

[10]U.S. General Accounting Office, Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost, GAO/HRD-93-41 (Washington, D.C.: March 1993).

[11]See Zimmerman and Janosky, pp. 213-23, and Zimmerman et al.

[12]Insofar as there were no equivalent findings for delay in being vaccinated with MMR, the outcome seems to vary by vaccine rather than insurance status. Even in light of the large differences one might expect among these insurance groups with regard to parental age, education, income, or hours of employment, the authors' pairwise comparisons found no difference that exceeded 4 months (7.8 months for insured children receiving DTP/3, 11.6 months for uninsured children).

associated with insurance status, such as access to transportation and parents' working hours. Even this study reported that, among the 84 percent of children immunized in the private sector, only 62 percent were fully immunized at age 2 compared to 73 percent of those who were immunized in public clinics.[13] In any case, although 68 percent of the physicians said they would refer children with no insurance coverage to public clinics, only 8 percent said they would refer Medicaid-covered children, who constitute most of the population eligible for VFC.[14]

Summary

The national immunization coverage of preschoolers is now much better than it was before the 1989-91 measles outbreak and the mild resurgence of pertussis and diphtheria in the late 1980s and early 1990s. At the outset of VFC, childhood immunization was at its highest and childhood diseases had reached historical lows. The studies we examined and the other sources of information available to us did not provide sufficient evidence to conclude that the major factor addressed by VFC, vaccine cost, has been a major barrier to immunization. It appears that efforts to address a variety of other barriers may be equally or more important in further improving immunization levels (see chapter 4).

[13]From a survey by Minnesota public health officials of the parents of 600 children randomly selected from a birth registry, cited in Zimmerman and Janosky, p. 214.

[14]CDC has recently cited an unpublished study as evidence to "support providing free vaccines for both uninsured and Medicaid children." In this study, Pennsylvania physicians who did not receive free vaccine said they were more likely to refer Medicaid and uninsured patients to public clinics for immunization than physicians who did receive free vaccine, although all physicians were more likely to refer these groups. The physicians believed that an average of 18 percent of the children in their practices were hindered from being immunized on time by unspecified economic concerns. However, the study lacked any measure of physicians' actual behavior, did not demonstrate that any children who were referred actually experienced greater delays in being immunized, and cannot attribute the differences in the physicians' self-reported referral patterns uniquely to their receipt of free vaccine. In any case, all the factors considered in the study, including receipt of free vaccine, accounted for less than a quarter of the variation in physicians' self-reported likelihood that they would refer uninsured children to public health clinics.

Chapter 3

Program Implementation

The Department of Health and Human Services announced that VFC would be implemented by October 1, 1994, and although progress has been made, as of March 1, 1995, VFC's implementation remained incomplete. Here, we describe the status of the seven basic implementation tasks we identified in July 1994: contract negotiation, vaccine distribution, provider enrollment, provider reimbursement, order processing and automation, accountability, and evaluation.[1] CDC's problems in integrating activities across these interdependent tasks and its general approach to the management of VFC's implementation raise concerns about its capacity to document whether the program has met its goals. Moreover, CDC cannot ensure that VFC will improve immunization in pockets of need and, consequently, eliminate conditions conducive to epidemics.

Status of Implementation Tasks

Since six of seven major implementation tasks we reviewed in July 1994 remained incomplete as of March 1, 1995, CDC cannot ensure that VFC will reach children at high risk of untimely immunization because (1) CDC does not know what proportion of providers have been enrolled or to what extent those who have been enrolled serve high-risk children and (2) the states are not required to report whether children in pockets of need are receiving free vaccine and, therefore, it will be difficult to attribute changes in immunization rates to the program's implementation.

Under CDC's implementation plans, the agency is to buy vaccines in bulk in sufficient quantities to meet the needs established by the states, which in turn are to distribute them to enrolled private and public providers and make the providers accountable for their use. Accordingly, implementing VFC has required CDC to harmonize the interests of federal financers, states, vaccine manufacturers, and immunization providers. The federal government, as the program's sole financer, has an interest in ensuring economical program administration and minimum vaccine waste and fraud. The states stand to benefit from the full federal financing of VFC vaccines, which removes the need for state contributions to finance vaccines for children eligible for Medicaid. The manufacturers, who are selling an increasing proportion of their vaccines to the federal government at a substantial discount, want strong accountability mechanisms to prevent the diversion of those vaccines to insured children from further eroding a dwindling private market. The immunization providers, while willing to receive free vaccine inasmuch as it limits their

[1]U.S. General Accounting Office, Vaccines for Children: Critical Issues in Design and Implementation, GAO/PEMD-94-28 (Washington, D.C.: July 1994).

need to finance vaccine purchases until patients can be billed, are concerned about the associated paperwork burden.

Vaccine Contracts

By October 1994, CDC had signed all 15 contracts necessary to buy vaccines in fiscal year 1995 even though 3 months before VFC was to begin operation, in July 1994, only 4 of the 15 had been signed. Two problems have subsequently emerged. First, CDC has, consistent with VFC legislation, encouraged manufacturers to compete by guaranteeing minimum vaccine orders to multiple bidders, but some states have objected that CDC's order processing methods do not permit them to guarantee physicians specific brands of vaccine.[2] Many physicians believe that different brands of vaccine are not interchangeable.

Second, CDC officials told us that the maximum doses of oral polio vaccine that can be purchased under the current contract will not meet the estimated needs of all the states for fiscal year 1995. This problem may only get worse, since 14 states and the District of Columbia had yet to begin routine ordering for private providers.[3] CDC expects to exceed the annual contractual cap of 10.8 million doses negotiated with the manufacturer by July 1995. This would result in a shortage of OPV for the VFC and Section 317 programs unless CDC uses OPV from the stockpile, which CDC officials describe as a last resort, or buys additional vaccine outside the existing contract. Buying OPV outside the contract at prices that exceeded the statutory caps would create questions about CDC's ability to comply with the law.[4] Meanwhile, the sole manufacturer of OPV contends that the states have overestimated their need for it and that additional purchases may not be necessary. Lacking accurate data on vaccine needs and usage, CDC cannot squarely address this issue.

Vaccine Distribution

CDC has had problems distributing VFC vaccines to private providers. At first, CDC officials indicated that the law did not permit it to reimburse manufacturers separately for delivery of vaccine purchased under the price caps. In apparent contradiction, after plans for a national distribution center were dropped in August 1994, CDC attempted to amend

[2]Under current contracting arrangements, such a guarantee might not be possible 100 percent of the time, but systems might be improved to optimize the satisfaction of providers' preferences.

[3]These 15 jurisdictions represent more than 1.3 million children, or more than 47 percent of the children younger than 2 who the states estimated would receive VFC vaccine from private providers.

[4]If the OPV contract does not permit the purchase of sufficient quantities of vaccine to meet VFC's needs, it will be important for CDC to give VFC's acquisitions priority over those made at state option.

its contracts with four vaccine manufacturers to provide separate payments for delivery services. With such arrangements, physicians in the 23 states and the District of Columbia that had planned to rely on the now abandoned center could then still receive their vaccines from the manufacturers. CDC solicited and received sole-source bids from four vaccine manufacturers by December 1994 but withdrew its solicitation in April 1995 because many states had made alternative distribution arrangements with CDC's financial assistance and because CDC believed a contract with one of the four manufacturers could not be negotiated. CDC officials reasoned that physicians would not participate in VFC if they were unable to receive all the vaccines they needed.

While the states that have decided to develop their own distribution systems will be fully reimbursed for distribution costs through VFC, these costs are not capped. Other than reviewing state funding requests, CDC has provided no guidance to the states on how to deal with distribution costs, which differ depending on state solicitation and contracting procedures. As of March 30, 1995, 15 of the 24 jurisdictions (23 states and the District of Columbia) that had expected to rely on a national distribution center had not begun routine vaccine shipments to private providers. They were still in various stages of planning and implementing their own distribution contracts or making other arrangements, such as relying on public health personnel to deliver vaccines, allowing private providers to pick them up, and establishing state-operated depots. At least 2 anticipated imminent signing of distribution contracts and vaccine shipping; 4 others had no plans to distribute vaccine to private providers in fiscal year 1995.

Provider Enrollment

Enrolled private and public immunization providers must complete the provider enrollment form, the provider profile, and patient eligibility forms. CDC delegated provider recruitment and enrollment to state health departments and state Medicaid agencies. In our prior review, we found that as of June 28, 1994, only 5 states had mailed enrollment forms to potential private providers. Moreover, CDC had no monitoring plans, intending instead to assess enrollment from initial vaccine orders. All but 4 of the 49 participating states had begun their enrollment within 3 months of when the program began in October 1994, and CDC had begun to collect data on the number of private and public sites that had been enrolled in each state. However, since CDC lacks accurate national data on the proportion and characteristics of enrolled providers, it cannot assess VFC's capacity to improve immunization rates overall or in pockets of need. Poor

monitoring could mean that the immunization of children eligible for Medicaid could be disrupted.[5]

Public Providers

CDC's goal in July 1994 was to enroll 90 percent of all public health providers by October 1, 1994, including federally qualified health centers, public health clinics operated by state health departments, and rural health clinics. CDC asserts that it had enrolled most public providers (8,062) as of March 30, 1995. However, as of April 3, 1995, CDC had no accurate estimates of the proportion of each of the major types of clinics that states had enrolled.[6]

Private Providers

CDC has been unable to adequately monitor the enrollment of either private providers in general or Medicaid providers in particular. CDC does not know the numbers of providers who are likely to administer pediatric care (that is, pediatricians, family practitioners, and osteopaths) and therefore cannot accurately assess the proportions of such providers who have been enrolled in VFC. In July 1994, CDC said that it hoped for 50-percent enrollment but had no state-specific goals. In January 1995, 46 states had begun their enrollment but only 30 of these could provide estimates of the proportions of immunization providers enrolled. Of these 30, only 15 reported 50-percent enrollment or more.[7] Of the remaining 15 states, 10 reported 11 to 49 percent enrollment and 5 reported 10 percent or less.

About 60 percent of the children who are eligible for VFC are also eligible for Medicaid and receive their health care through providers enrolled in that program. HCFA plans to terminate Medicaid vaccine payments in October 1995 where VFC vaccines are available to private providers. Thus, monitoring the proportions of Medicaid physicians who have enrolled in VFC is important to ensure that Medicaid beneficiaries' access to immunization through their regular providers will not be disrupted. However, it is not clear whether HCFA can assess Medicaid beneficiaries' access to VFC-enrolled providers in order to determine when it is prudent to end these payments. Although some states have information on the

[5]Medicaid providers that see only small numbers of children might not enroll in VFC to avoid becoming involved in an additional program.

[6]Federally qualified health centers and rural health clinics are the only types of providers from which underinsured children may receive free VFC vaccine. Tracking their enrollment is therefore particularly important. Data from the Health Care Financing Administration (HCFA) and from CDC suggest that 82 percent of rural health clinics have been enrolled. CDC also reports that many states indicate that all their health department clinics have been enrolled.

[7]Of these 15, 10 were capable of expediting enrollment because they either had begun universal vaccine distribution since VFC or had implemented universal distribution programs before VFC. The 3 states reporting 90-percent enrollment or more had had universal programs before VFC, but they serve less than 1 percent of the children younger than 2 who are likely to be immunized with VFC vaccines

enrollment of Medicaid providers, federal officials have not asked them to collect or report it.

Provider Reimbursement

Under the law, VFC providers' fees for administering vaccine were to be based on their actual costs for providing this service. Accordingly, HHS has set caps on providers' administration fees. However, it has based these caps on physicians' prevailing charges instead of costs. Consequently, in several states, permissible fees under VFC have exceeded Medicaid vaccine administration fees by as much as $10. CDC's rationale for using prevailing charges was that data on the cost of administering vaccine were insufficient when it developed VFC's reimbursement policy and that physicians would not otherwise enroll. We noted in July 1994 that this policy might create burdens for parents, who may have to pay more than under a fee schedule based on administration costs, as stipulated in the law.[8]

On January 31, 1995, HCFA officials told us that they had engaged the Center for Health Policy Studies to collect data for designing cost-based maximum fee schedules, but as of May 12, 1995, the research protocol was still under review at the Office of Management and Budget. Since it was unavailable to us, we cannot comment on the cost study's conclusions and recommendations. Meanwhile, CDC is allowing providers to apply charge-based fees for administering vaccine until a new fee schedule becomes ready on October 1, 1995, when VFC begins its second year.

Order Processing and Automation

To assist the states in ordering, tracking, and recording the costs of VFC vaccines, during fiscal year 1994 CDC developed and distributed a vaccine-management system called VACMAN at a cost of just under $1 million. This system was designed to run on a desktop computer supplied by CDC exclusively for this purpose and to link CDC by modem, through an electronic bulletin board, with the 64 immunization projects nationwide. VACMAN was not designed to meet critical VFC program requirements such as identifying children in need of vaccine and tracking those receiving vaccines through the program. Rather, it was designed primarily to support order processing. Even in this limited area, however, VACMAN's usefulness to the states has been sharply diminished by gaps in performance and capability that have forced some states to turn instead to

[8]U.S. General Accounting Office, Vaccines for Children: Critical Issues in Design and Implementation, p. 2.

manual or other automated systems to supplement or replace what VACMAN was intended to provide.

To ensure that the system would be available by the program's October 1, 1994, starting date, CDC decided not to follow sound systems-development practices.[9] Specifically, CDC did not (1) adequately assess its users' needs, (2) perform alternative systems design and cost-benefit analyses, or (3) perform independent quality-assurance testing of the software. CDC thus limited the program support that VACMAN can offer, failed to establish a contingency plan for VACMAN's telecommunications links, and left itself unable to ensure that system hardware, software, or communications will operate as expected. Although VACMAN is still not complete, CDC plans multiple revisions to the software through the end of this year.

Because of the time constraints, and CDC's decision not to undertake a comprehensive alternative design analysis, it did not consider the range of VFC functions that technology could support. CDC therefore locked itself into a design that may not have been the best alternative and that lacks critical program elements. For example, VACMAN's technical interface capability falls seriously short of meeting the states' needs. The states said that for VACMAN to be useful to them, they need to link it with other systems and databases but in many cases they cannot. Further, CDC failed to take advantage of existing databases, such as state welfare and Medicaid systems, that could support the identification of children who need immunization.

By not adequately involving VACMAN's users in identifying their needs before CDC implemented the system, the agency created a system that fails to support many of VFC's functions. As one state representative said, "At this point we are not sure what the system can and cannot do because of continual changes; [the] haste in which the government has dumped this thing [on us] has contributed to most of the problems." To identify the states' needs, CDC this past January conferred with VACMAN's users, who identified more than 100 problems. One key problem they noted was that VACMAN does not provide the states with overall project fund balances; as a result, they may not know whether they have funds to cover orders as they place them. Similarly, the system does not indicate whether a vaccine is on back order; the states therefore cannot easily determine whether or when an order will be filled. Officials in 29 states said that they operate

[9]The National Institute of Standards and Technology issued Federal Information Processing Standards publications 38 and 64 covering software development life-cycle documentation guidelines and evaluation methodology.

other systems to track and manage vaccines, even though this sometimes involves dual data-entry and redundant operations. In revising VACMAN this year, it will be imperative for CDC to correct these and other problems with the original design.

CDC disabled some of VACMAN's original features that have not, therefore, been used. CDC disabled private-provider ordering functions when the national system for distributing vaccines to providers was dropped. The states can use VACMAN only for bulk ordering, thus limiting their ability to track and account for the vaccines ordered by private providers. Moreover, the states perceive VACMAN's accountability functions as limited—only 8 states reported that VACMAN meets all their accountability needs.

Finally, both CDC and the states rely on VACMAN's electronic bulletin board as a 24-hour repository of order information until it is entered into CDC's mainframe computer for review and transmission to vaccine manufacturers. However, CDC performed no independent quality-assurance testing of the bulletin board and the network environment and, therefore, has no contingency plan to guide operations if it fails.

Accountability

Believing that strict accountability measures, such as requiring providers to report vaccine usage, might prevent them from participating, CDC initially minimized providers' accountability requirements and delegated responsibility for them to the states. In May 1994, CDC advised the states that "although measures against fraud and abuse are appropriate, the effect such measures will have on provider participation must be considered."[10] CDC mandated only that the states require providers to complete three enrollment documents.[11]

CDC's initial plan was to use the providers' own estimates of their vaccine needs as the basis for vaccine accountability. We noted in July 1994 that this plan was inadequate and that CDC lacked any independent means of verifying state vaccine needs. Even though providers were already legally required to maintain data on all immunizations and had been advised to collect similar data under ACIP recommendations, CDC did not require the

[10]Centers for Disease Control and Prevention, Vaccines for Children Operation Guide (Atlanta: May 1994), p. 42.

[11]Centers for Disease Control and Prevention, Vaccines For Children Operations Guide, p. 22. The three enrollment documents are the provider's profile, the provider's enrollment form, and the patient eligibility form.

states to collect actual usage information from the providers that received free vaccine.[12] Thus, we concluded in our earlier report that it would not be able to detect fraud and waste. Moreover, providers' enrollment remains low, despite VFC's minimal accountability requirements.

Reversing policy, on November 14, 1994, CDC gave the states 1 month to develop comprehensive accountability plans for their supplies of free vaccine. These plans contain a variety of measures, including plans in many states to compare providers' profiles and ordering patterns to external databases such as immunization registries. But since no states have reported to CDC, it still cannot distinguish between the number of children who have been immunized under VFC and the number of doses of vaccine that have been distributed, nor can it accurately assess vaccine waste.

The major federal accountability requirement has been that providers estimate the number of their patients who are eligible for VFC and their vaccine needs. However, most states report that providers "greatly" or "somewhat" overestimate these numbers. CDC has found that several states relying on these estimates have projected vaccine needs that exceed the total numbers of children in the appropriate age ranges. Therefore, CDC has dropped its plans to use such data as a basis for accountability, engaging a contractor in February 1995 to study alternative measures.

In the absence of better accountability plans, CDC has no way to ensure that VFC is reaching the target population, let alone pockets of underimmunization. Under CII, random-digit-dialing surveys of immunization projects in various states and cities will provide data on immunization rates by certain demographic criteria. However, when the results become available, they will neither identify specific areas within these states and cities where children are at highest risk of not being immunized nor distinguish between VFC's effect and that of other, concurrent efforts to improve children's immunization. Further, their capacity to assess high-risk populations may be compromised by the reliance on households with telephones as a sampling frame.

[12]Public Law 99-660, 100 Stat. 3774 (1986), 42 U.S.C. sec. 300aa-25; U.S. Department of Health and Human Services, Public Health Service, "Standards for Pediatric Immunization Practices," Morbidity and Mortality Weekly Report, 42:RR-5 (April 23, 1993), 3. Standard 9 states that "Providers use accurate and complete recording procedures." Standard 14 suggests that "Providers conduct semi-annual audits to assess immunization coverage and to review immunization records in the patient population they serve."

Evaluation

As of May 1, 1995, CDC had released no plans for evaluating the VFC program, and 31 of the states we interviewed in December 1994 had no such plans. The states that did generally acknowledged that they were not intended to evaluate its effect (versus assess its implementation) or could not distinguish VFC from other factors. Simple comparisons of preprogram and postprogram immunization rates or proxy variables will not allow evaluators to attribute any changes to VFC rather than to other simultaneous activity within the larger, ongoing effort among the states to increase childhood immunization. Forty states reported initiating related programs at or near the time when VFC began. No direct effect could be expected in the states that had universal purchase programs prior to VFC, since VFC represents only a change in their source of financing for vaccine purchases.[13]

CDC officials reported that their draft VFC evaluation plans focused on program implementation, which CDC has begun to examine through periodic surveys of state immunization personnel.

Increasing Implementation and Operations Burden

In its haste to implement VFC by October 1, 1994, CDC intended to complete some tasks as the implementation burden decreased once the program had begun. However, the burden is unlikely to decrease. As the program progresses to year 2, incomplete tasks from year 1 are added to the current year's program operations, such as ongoing program enrollment and accountability activities, and to the subsequent year's implementation needs, such as the renewal of vaccine and distribution contracts.

Just as the failure to complete a task contributes to problems in program implementation in any given year, these problems are compounded over time, increasing the work of agency staff. Moreover, since implementation tasks are interdependent, those that remain incomplete in one year may actually prohibit the completion of others in subsequent years. For example, without adequate accountability mechanisms, critical data on vaccine use in fiscal year 1995 are unavailable for negotiating contracts for vaccines and their distribution in fiscal year 1996. The absence of such information similarly complicated negotiations with manufacturers in fiscal year 1994, as exemplified by the controversial limits incorporated in the OPV contract.

[13]However, it is possible that these states will incorporate new vaccines in their programs more quickly than they would have when state funding was required.

CDC is not able to ensure that VFC's problems in contracts, vaccine ordering and distribution, provider enrollment and reimbursement, accountability, and evaluation will be resolved before or within the next fiscal year. Some of the program's failings, such as low enrollment among private providers, might improve over time, but without better monitoring of VFC's implementation, CDC cannot guarantee that the children who need VFC vaccine will get it, and it is poorly prepared to ensure a safe transition or good coordination between existing programs and VFC.

Summary

We found ongoing problems in six of the seven areas of program implementation we examined. Although contract negotiation and enrollment of public health providers are largely complete, the enrollment of private providers appears to be low. While HCFA conducts a cost study, VFC policies governing provider fees remain inconsistent with the law. At least 15 jurisdictions had not begun routine shipments of vaccine to private providers by March 1995. Moreover, VFC's automated order processing system was not developed in conformance with federal guidelines and, consequently, supports limited program functions and fails to meet important user requirements. CDC's accountability plans do not permit it to distinguish the number of children immunized with VFC vaccine from the number of doses of vaccine distributed and thus limit its capacity to monitor vaccine waste and diversion. Finally, evaluation plans were not ready as late as May 1995.

Collectively, these facts raise concerns about VFC's management and its coordination with other immunization programs. VFC's management, split across HCFA, CDC, and the states, offers little assurance of a smooth transition between VFC and other immunization programs. For example, while VFC operates in conjunction with Medicaid's immunization efforts, the two programs have not been adequately coordinated. HCFA has therefore been unable to set criteria for cut-off dates for vaccine reimbursement under Medicaid, and data on Medicaid providers critical for developing VFC's provider-enrollment goals are not available.

Chapter 4

Promising Options

Just as there are many barriers to the immunization of children at high risk of not being immunized, so increases in their immunization rates have been attributed to many efforts to overcome these barriers. Some of these efforts may entail smaller federal costs than those anticipated for VFC and may be equally or more effective. The complex nature of underimmunization requires varied interventions based on sound research. Thus, it is important that limited resources are targeted to the most important potential barriers and populations at highest risk.

CDC-funded studies describe two strategies that have demonstrable promise for improving immunization rates. One is to reduce missed opportunities for immunization during children's regular contacts with their health care providers. This has been done by establishing clinic audit and feedback systems and reminder and recall systems.[1] For example, immunization registries have received much attention; they not only provide information on children's immunization status but may also help monitor immunization, record children's adverse reactions, and account for vaccine.[2] Another strategy is to coordinate immunization services with large public programs such as the Special Supplemental Food Program for Women, Infants, and Children (WIC) and Aid to Families with Dependent Children (AFDC) that cover children who are known to be at high risk of not being immunized on time. Some other interventions that have been suggested include strengthening state, local, and clinic infrastructures, improving parental education, offering incentives to states or providers, and requiring that insurance cover immunization.

Reducing Missed Opportunities

Underimmunized children in major American cities have had many contacts with health care providers without receiving indicated vaccines.[3] The missed opportunities resulted from not administering vaccines simultaneously, not compressing the vaccination schedule for children known to be behind schedule, not knowing children's immunization status, and following false contraindications. Table 4.1 shows the immunization

[1]See, for example, M. Chaney, "Evaluation of Vaccination Strategies in Public Clinics—Georgia, 1985-1993," Morbidity and Mortality Weekly Report, 44:16 (1995), 323-25.

[2]By tracking doses of vaccine administered, registries could also help estimate vaccine waste and projected needs within the Medicaid or VFC programs. See National Vaccine Advisory Committee, Subcommittee on Vaccination Registries, "Developing a National Childhood Immunization Information System: Registries, Reminders and Recall," Washington, D.C., 1994.

[3]See, for example, A. S. Bates et al., "Risk Factors for Underimmunization in Poor Urban Infants," Journal of the American Medical Association, 272:14 (October 12, 1994), 1105-9, and J. S. Gindler et al., "Successes and Failures in Vaccine Delivery: Evaluation of the Immunization Delivery System in Puerto Rico," Pediatrics, 91:2 (February 1993), 315-20.

levels for 2-year-old children observed in the four CDC-sponsored studies discussed in chapter 2 and projected improvements in them that could be achieved by reducing such missed opportunities.

Table 4.1: Percentage of Actual and Potential Vaccination Coverage Among 24-Month-Old Children by Individual Vaccine Doses and Study Site, 1991-92

Study site	Vaccine[a]/dose	Actual	Potential[b]	Difference
Baltimore	DTP/DT/3	85%	93%	8%
	DTP/DT/4	58	74	16
	Polio/3	65	81	16
	MMR/1	80	89	9
Los Angeles	DTP/DT/3	54	62	8
	DTP/DT/4	26	34	8
	Polio/3	34	50	16
	MMR/1	39	48	9
Philadelphia	DTP/DT/3	82	85	3
	DTP/DT/4	57	67	10
	Polio/3	68	79	11
	MMR/1	87	94	7
Rochester	DTP/DT/3	94	99	5
	DTP/DT/4	75	96	21
	Polio/3	80	95	15
	MMR/1	90	96	6

[a]DTP/DT = diphtheria and tetanus toxoids and pertussis vaccine/diphtheria and tetanus toxoids. MMR = measles-mumps-rubella vaccine.

[b]Assumes all missed opportunities to vaccinate had been eliminated.

Source: Morbidity and Mortality Weekly Report, 43:39 (October 7, 1994), 711.

Noting the problem of missed opportunities, one CDC study reports that, in Georgia clinics,

> "Providers often told the parents of young infants to bring the children back in 2 months, even after children had fallen 2 or 3 weeks (or even months) behind. Most clinics in Georgia were not using the minimal time intervals between doses unless a child started extremely late or was getting ready for school or day care. Everybody else was automatically told to come back in 2 months—more by habit than because of medical judgment."[4]

[4]Eugene Dini, "Assessment as a Motivational Tool," 26th National Immunization Conference Proceedings (Atlanta: Centers for Disease Control and Prevention, March 1993), pp. 55-59.

Consequently, 90-percent on-time levels for children 12 months old dropped to 50 percent or 60 percent for children 18 months old. Many children had not received their third dose of diphtheria-tetanus-pertussis vaccine by 9 months and were consequently ineligible for their fourth dose at 15 months. The assessment of immunization practices combined with feedback to immunization providers and the development of reminder and recall systems are two specific strategies that show some promise for helping reduce missed opportunities.

Immunization Practice Assessment and Feedback

Routinely evaluating children's immunization dates as recorded in clinic records has been coupled with feedback to health care staff that includes estimates of coverage levels by site and by age, lists of children missing immunizations, and reasons such as late starts, dropouts, and poor documentation. Depending on the prevalence of particular reasons for missed immunizations, providers may then be advised to consider postpartum appointments, reminder and recall systems, or accelerated immunization schedules.

CDC's Immunization Action Plan (IAP) grantees are required to use this audit strategy, and CDC plans to support their efforts to apply it in all public clinics, having developed and distributed software for this purpose. However, the 64 grantees and 24 urban areas are visited only about once every 6 to 9 months by staff from CDC's Program Operations Branch. Potential extensions of this immunization practice assessment and feedback technique would cover Community and Migrant Health Centers under the Bureau of Primary Health Care, managed care organizations, and private providers.

When Georgia public health clinics piloted the strategy, the percentage of children who missed opportunities for immunization because they had failed to receive simultaneous immunizations fell from more than 25 percent in 1986 to less than 5 percent in 1991. Simultaneously, the proportion of 2-year-old children who had received four doses of DTP, three doses of OPV, and one dose of MMR rose from about 35 percent to nearly 70 percent. These changes cannot be attributed with certainty to the assessment and feedback activities, but a relationship is suggested. It should be noted, however, that the clinic assessments were "the most time-consuming activity performed by the Georgia field staff," taking from 20 to 25 percent of the time for seven staff members.[5] Thus, careful evaluation of the strategy's cost-effectiveness is warranted.

[5]Dini, p. 55.

Reminder and Recall Systems

Reminder and recall systems prompt providers of immunization due dates and recall parents when the dates are missed. Such systems focus on children as soon as they become eligible for immunization and when they fall off schedule. Whether manual or automatic, such systems may send messages by telephone or mail. They may be limited to periodic review of particular providers' records or incorporated in a comprehensive statewide immunization registry.

Through a reminder and recall system attempted in public health departments in 14 Georgia counties, 36 percent of the children randomly assigned to receive a telephone reminder visited the health department within 30 days. Only 28 percent of the children whose households were not assigned to be contacted visited the department.[6] Thus, visiting increased modestly.

Similar increases have been achieved by systems using letters, postcards, personal telephone calls, and home visits, but costs for materials and labor have precluded their use by some state and local health departments and private practitioners.[7] Initial costs for automated dialing arrangements are high ($10,000 for the first year), but subsequent costs are lower. These arrangements may actually be more cost-effective than reminders relayed by mail or personal calls because they require less labor. It should also be noted that the percentage of households successfully contacted may vary significantly depending on demographic characteristics. For example, Hispanic and other ethnic children had contact rates of only 35 percent and 42 percent in one study.[8] Messages had their greatest effect for children who were late for MMR, the third or fourth dose of DTP, or the third dose of OPV (particularly important insofar as on-time immunization rates appear to decrease with age).[9]

[6]Robert W. Linkins et al., "A Randomized Trial of the Effectiveness of Computer-Generated Telephone Messages in Increasing Immunization Visits Among Preschool Children," Archives of Pediatric and Adolescent Medicine, 148 (September 1994), 908-14.

[7]E. Byrne et al., "Infant Immunization Surveillance: Cost vs. Effect: A Prospective, Controlled Evaluation of a Large-scale Program in Rhode Island," Journal of the American Medical Association, 212 (1970), 770-73; T. Quattlebaum, P. Darden, and L. Sperry, "Effectiveness of Computer-Generated Appointment Reminders," Pediatrics, 88 (1991), 801-5.

[8]Linkins et al., p. 911. See also P. Stehr-Green et al., "Evaluation of Telephoned Computer-Generated Reminders to Improve Immunization Coverage at Inner-City Clinics," Public Health Reports, 108 (1993), 426-30.

[9]F. Cutts et al., "Monitoring Progress Toward U.S. Preschool Immunization Goals," Journal of the American Medical Association, 267 (1992), 1952-55.

Linking Immunization Services to WIC and AFDC

WIC grants the states funds to help low-income pregnant women and young children obtain food. Pilot projects coordinating immunization services with WIC have assessed a child's immunization record when the mother visits the WIC clinic to obtain food vouchers, usually every 2 months. Among other WIC-based interventions, the mother's schedule for receiving food vouchers may be made contingent on her child's up-to-date immunization, with more frequent visits required when the child is behind schedule. Children who need immunization may be referred either to their usual source of care or to an on-site immunization clinic. In interventions in New York City, making the schedule for receiving vouchers contingent on immunization or escorting the mother and child to a nearby immunization clinic substantially increased immunization rates among WIC participants. More data are needed to carefully evaluate the relationship between the voucher sanction and withdrawal from the WIC program.

Nonetheless, WIC is especially well-suited to coordination with immunization services because participants typically visit a program site with some regularity and the program focuses largely on children younger than those encompassed in AFDC, Medicaid, or even Head Start. More than 40 percent of the nation's preschool children participate in WIC during their first year of life, although the figure varies from state to state. Moreover, surveys following the 1989-91 measles epidemic found that between 29 and 63 percent of preschool children with measles were enrolled in WIC.[10]

It might also be possible to raise immunization rates by better integrating immunization services in the AFDC, Medicaid, and Early Periodic Screening, Diagnosis, and Treatment programs. Ten states, at their own initiative, now have waivers under AFDC to link immunization requirements to the receipt of AFDC benefits.[11] As currently applied, this approach tends to rely on punitive reductions in AFDC grants and generally holds only parents accountable for immunization, including no sanctions for providers who refer Medicaid patients to public clinics at higher rates than privately insured patients. Evaluations of this approach are still in progress but early results appear to be promising.

[10]S. Hutchins et al., "WIC Immunization Experience: An Appropriate Setting for Immunization Services," 27th National Immunization Conference Proceedings (Atlanta: Centers for Disease Control and Prevention, 1994), pp. 149-52.

[11]These states are Colorado, Delaware, Florida, Georgia, Indiana, Maryland, Michigan, Mississippi, Montana, and South Carolina. However, South Carolina does not plan to exercise its waiver.

Summary

Evidence suggests that various factors that lead to missed opportunities to immunize children can be successfully addressed by systems that remind providers that immunizations are due and recall parents when appointments or vaccines have been missed. Such tracking systems can operate at the clinic level or as part of more comprehensive immunization registries. Similarly, missed opportunities have been reduced when the records of immunization clinics are audited and the results of these audits are made known to clinic staff. Finally, the states' integration of immunization services into WIC and other programs that cover large segments of the preschool population shows promise for raising timely immunization coverage among children known to be at high risk of delayed immunization.

Conclusions, Matters for Consideration, and Agency Comments

Conclusions

CDC officials have noted that

"The experience of immunization programs worldwide has identified three factors critical to success: (1) establishment of measurable objectives that are continuously evaluated; (2) quality control of program performance, and (3) research to solve operational problems."[1]

Inasmuch as studies of past outbreaks suggest that disease is greatest in areas of high population density where substantial numbers of preschool children are not immunized on time, it seems reasonable to identify, emphasize, and monitor immunization coverage in these areas, which is masked when coverage goals and measures are not broken down by age, risk, and residence.

While it appears that the greatest threat of disease is currently presented by concentrations of underimmunized children rather than widespread underimmunization in the general population, both CII's and VFC's goals emphasize raising immunization rates in the population at large. Even if VFC were fully implemented, its accountability and evaluation mechanisms could not track its effect where the need for timely immunization is greatest. As we noted in chapter 2, CDC's own analyses of geographic patterns in measles cases suggest that it may be possible to enhance disease prevention efforts by targeting special efforts to such areas.

Major studies of underimmunized children indicate that free vaccine was generally available to them before VFC. Evidence is insufficient to conclude that vaccine cost has been the major barrier for the parents of these children. Thus, even a fully functional VFC is not likely to prevent outbreaks of vaccine-preventable disease. Data on underimmunized children in major metropolitan areas indicate that supplementary action independent of making vaccine free will be required and that efforts other than VFC may hold greater promise.

CDC has not collected important data for measuring VFC's implementation and supporting its evaluation. Specifically, CDC lacks figures on the proportions of enrolled public health providers, private providers likely to immunize children, and Medicaid providers of pediatric care. It does not know the proportions of eligible children served by these providers or what provider enrollment levels are necessary to meet and maintain its goal of immunizing 90 percent of the nation's children with most antigens

[1]F. T. Cutts et al., "Monitoring Progress Toward U.S. Preschool Immunization Goals," Journal of the American Medical Association, 267:14 (April 8, 1992), 1952-55).

by 1996. Moreover, this overall goal does not account for the potential for the outbreak of specific diseases where underimmunization is greatest.

Some of CDC's implementation decisions may undermine its goals. For example, CDC does not require VFC providers to report the vaccination of particular children; this is inconsistent with CDC's acknowledgment, under CII, of the importance of tracking systems. Without knowing what doses providers actually administer or to whom, CDC will not be able to sort between the numbers of children immunized with VFC vaccine and the amount of vaccine distributed. The states' use of Medicaid and other data for accountability purposes (such as vaccine-usage reports, doses-administered reports, and immunization registry data) could serve as a foundation for basic tracking and evaluation.

Missed opportunities are more closely linked to underimmunization than vaccine cost or parental attitudes. Promising alternatives for increasing immunization rates include reviewing providers' records and providing feedback, using reminder and recall systems more broadly (perhaps in conjunction with registries), and incorporating voucher incentives for up-to-date immunization of children covered by WIC. All these strategies are operating in many places. They share an emphasis on reducing missed opportunities for immunizing children when they make contact with their medical providers. They would require further examination before implementing them broadly but seem promising for wider application.

Matters for Consideration

The Congress may want to consider refocusing VFC's goal from the improvement of general immunization rates to the achievement of higher immunization rates in pockets of need, where conditions are ripe for disease outbreaks among underimmunized children. A program with immunization targeted to pockets of need should be more cost-effective than the current approach. In conjunction, enrollment, accountability, automation, and evaluation efforts need to be adjusted to focus on children who are at greatest risk for delayed immunization. For example, reminder and recall or tracking systems might help identify and reach them.

Agency Comments and Our Response

We shared a draft of this report with responsible officials of the Department of Health and Human Services on June 10, 1995, and received oral comments from them on June 13, 1995. (We also orally summarized our findings in an exit conference with HHS officials on May 2, 1995, and

received oral comments.) The officials stated that they did not agree with our conclusions and believed that our views were not balanced. However, the comments they provided were directed primarily to tone and technical matters. We have incorporated these comments in the final report where appropriate.

1994 Advisory Committee on Immunization Practices Immunization Schedule

Vaccine	Birth	Months 1-2	2	4	6	6-18	12-15	15	4-6 years
DTP[a]			x	x	x			x	x
OPV[b]			x	x	x				x
MMR[c]							x		x
Hib conjugate[d]									
HbOC/PRPT[e]			x	x	x		x		
PRP-OMP[f]			x	x			x		
Hep B[g]									
Option 1	x	x				x			
Option 2		x		x		x			

[a]Diphtheria and tetanus toxoids and pertussis vaccine.

[b]Oral polio vaccine.

[c]Measles-mumps-rubella.

[d]Haemophilus influenza type B conjugate.

[e]Haemophilus influenza oligosaccharide conjugate/polyribose phosphate tetanus.

[f]Polyribose phosphate-outer membrane protein.

[g]Hepatitis B.

Note: Since this schedule was issued, ACIP, the American Academy of Pediatrics, and the American Academy of Family Physicians have agreed on a harmonized immunization schedule, which is available in CDC, The Race to Vaccinate: The Year 2000 and Beyond, 29th National Immunization Conference (Washington, D.C.: U.S. Department of Health and Human Services, Public Health Service, 1995).

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